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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,772	11/14/2003	Yoshihiro Mori	09496/0200199-US0	8762
7278	7590	10/31/2006	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			CRAIG, PAULA L	
			ART UNIT	PAPER NUMBER

3761

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/713,772

Applicant(s)

MORI ET AL.

Examiner

Paula L. Craig

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

1. The objection to Claim 2 is withdrawn. For the rejections of Claims 1-6, Applicant's arguments filed August 25, 2006 have been fully considered but they are not persuasive. Applicant argues that Brugger does not teach the calculating unit calculating a measurement value and a theoretical value of the blood concentrations, the evaluation unit evaluating whether the measurement and theoretical values are approximately equal, and using the result to determine the performance of the blood pump or the blood purifier. However, Brugger clearly teaches measuring blood concentrations in both the arterial and venous blood circuits (upstream and downstream sensors for measuring pre-treatment and post-treatment hematocrit respectively, Fig. 11, col. 24, lines 3-21). The values reported by these sensors establish the measurement value. Brugger teaches calculating a theoretical value for the blood concentrations based on parameters including a preset blood flow rate and a preset blood purifying rate (col. 21, line 24, to col. 24, line 33). Applicant argues that Brugger teaches controlling the filtration rate based on comparison between the fluid reduction value derived from the pre-and post-treatment hematocrits, and the desired filtration fraction value ("FF") prescribed by the attending physician, rather than the claimed parameters. Brugger teaches that hemofiltration or dialysis involves removing blood from the patient, removing waste liquid which includes the toxins, supplying fresh fluid to the patient to replace some or all of the liquid removed, and returning the blood to the

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patient (col. 1, lines 23-50). Brugger teaches that hemofiltration usually involves ultrafiltration, meaning that the amount of liquid replaced is somewhat less than the amount removed from the blood (col. 1, lines 42-50). Brugger teaches that FF is the desired percentage of fluid to be removed from the blood stream through the hemofilter 34, with the desired FF determined by the therapeutic objectives of the treatment in removing toxins from the blood, and the performance characteristics of the hemofilter (col. 21, lines 42-44). Some of the fluid is then replaced, with the percentage of fluid replaced determined by the ultrafiltration rate or UFR (col. 20, lines 52-54). The RFR is the replacement flow rate of the replacement fluid (col. 20, lines 48-51). Brugger teaches the FF being related to the blood flow rate ("BFR") by the equations given in col. 21, line 39, and col. 22, line 59, and col. 31, line 62 to col. 32, lines 14. Brugger also teaches that the prescribing physician may simply prescribe a blood flow rate and use preset ordinary values for the other parameters, such as an FF of 30% (col. 20, lines 41-54 and col. 21, lines 34-53, and col. 31, line 62 to col. 32, line 14). Applicant's specification teaches that the preset blood purifying rate is the preset water removal rate (specification, page 12, lines 8-9, and Claim 2). It therefore appears that the FF of Brugger is the equivalent of Applicant's claimed blood purifying rate, while the BFR of Brugger is the same as Applicant's claimed blood flow rate. Brugger also teaches using the calculations of the measurement and theoretical values to determine performance of the blood pump and blood purifier (col. 6, lines 53-61, col. 10, lines 2-9, col. 20, lines 54-58, col. 22, lines 47-51, col. 24, lines 29-45, col. 31, lines 42-47).

***Claim Rejections - 35 USC § 102/103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejections of Claims 1-6 under 35 U.S.C. 102 (a) as anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brugger (U.S. Patent No. 6,554,789) are maintained for the reasons of record, as well as the reasons described above.

***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571 )272-5964. The examiner can normally be reached on 6:30AM-3:00PM M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paula L Craig  
Examiner  
Art Unit 3761

PLC

TATYANA ZALUKAEVA  
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